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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/972,301	11/18/1997	TIMOTHY A. COLEMAN	325800-588(P	5422

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HUMAN GENOME SCIENCES INC
14200 SHADY GROVE ROAD
ROCKVILLE, MD 20850

EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/972,301

Applicant(s)

COLEMAN ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 137-151, 187, 188, 190-196, 198-202, 204 and 206-208 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 137-151, 204 and 206-208 is/are allowed.
- 6) ☒ Claim(s) 187, 188, 190-196 and 198-202 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment received 19 December 2003 has been entered in full. Claims 1-136, 152-186, 189, 197, 203 and 205 are canceled. Claims 137-151, 187, 188, 190-196, 198-202 and 206-208 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claims 152-186, 189, 197, 203 and 205 under 35 U.S.C. § 112, first paragraph, regarding scope of enablement, as set forth at pp. 2-5 of the previous Office Action (Paper No. 33, 30 September 2003) is *withdrawn* in view of the canceled claims (amendment received 19 December 2003).

The rejection of claims 152-186, 189, 197, 203 and 205 under 35 U.S.C. § 112, first paragraph, regarding inadequate written description, as set forth at pp. 5-6 of the previous Office Action (Paper No. 33, 30 September 2003) is *withdrawn* in view of the canceled claims (amendment received 19 December 2003).

The rejection of claims 171, 173-175, 177-179, 181-183, 185, 186, 203 and 205 under 35 U.S.C. § 102(b) as set forth at pp. 6-7 of the previous Office Action (Paper No. 33, 30 September 2003) is *withdrawn* in view of the canceled claims (amendment received 19 December 2003).

35 U.S.C. § 112, First Paragraph

Claims 187, 188, 190-196 and 198-202 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed invention wherein the recited protein comprises SEQ ID NO: 2, does not reasonably provide enablement for the claimed invention reciting fragments of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis for this rejection is set forth at pp. 2-5 of the previous Office Action (Paper No; 33, 30 September 2003).

Applicant argues (p. 8, response) that the amendment of the claims to “consisting of” obviates the rejection. This has been fully considered but is not found to be persuasive. As discussed in the previous Office Action, fragments of SEQ ID NO: 2 are not enabled, as the specification does not teach the skilled artisan how to use such fragments. It is not clear what the activities of such fragments may be, and the claims do not recite a particular biological activity retained by the fragments.

Due to the large quantity of experimentation necessary to determine how to make a useful fragment of SEQ ID NO: 2, the lack of direction/guidance presented in the specification regarding fragments, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing the unpredictability of mutation on overall structure and function, and the breadth of the claims which fail to recite particular biological activities and also embrace a broad class

of structural fragments, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 187, 188, 190-196 and 198-202 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The basis for this rejection is set forth at pp. 5-6 of the previous Office Action (Paper No; 33, 30 September 2003).

Applicant argues (p. 8, response) that the amendment of the claims to "consisting of" obviates the rejection. This has been fully considered but is not found to be persuasive. As discussed in the previous Office Action, the claimed genus of fragments of SEQ ID NO: 2 are not adequately described. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of a length of fragment. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying

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characteristics, the specification does not provide adequate written description of the claimed genus.

Conclusion

Claims 137-151, 204 and 206-208 are allowable. Claims 187, 188, 190-196 and 198-202 are not allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

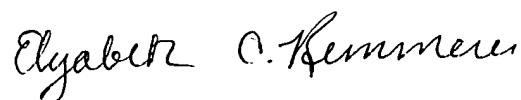
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (571) 272-0874. The examiner can normally be reached Monday through Thursday from 7:00 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (571) 272-0871.

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The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



ECK

ELIZABETH KEMMERER
PRIMARY EXAMINER